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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stephane Follonier

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EXAMINER

YU, MELANIE J

ART UNIT

PAPER NUMBER

1641

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/670,912	Applicant(s) FOLLONIER ET AL.	
	Examiner MELANIE YU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 16-33, 59, 60 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 16-33, 59, 60 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 January 2009 has been entered.

Status of the Claims

2. Claims 1-12, 14, 15, 34-58 and 61 have been canceled. Claims 13, 16-33, 59, 60 and 62 are pending and are examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 13, 16-18, 20, 24-30, 33, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (US 6,020,207) in view of Evans (US 7,129,510).

Liu teaches a system comprising:

a) a least one light emitting element wherein the light emitting element is a laser (col. 5, lines 31-34);

b) a primary light connecting element (optical fiber used as light input, col. 3, lines 10-14);

c) a measuring cell comprising at least one tube capable of guiding light through a fluid in the inner volume of the tube (sensor cell is capillary tube, col. 2, line 63-col. 3, line 1), wherein the tube comprises: a first opening (left side of tube, 10, where fiber, 18, is inserted, Fig. 3; proximal end of tube, col. 3, lines 15-19), a second opening (right side of tube, 10, where fiber, 20, is inserted, Fig. 3; distal end of tube, col. 3, lines 15-19), and an inner surface coated with at least one binding agent capable of binding at least one target introduced into the at least one tube (col. 2, lines 11-13);

d) a secondary light connecting element (optical fiber positioned at end of cell, col. 2, lines 18-20); and

e) at least one light detecting element (col. 5, lines 39-49),

wherein the light emitted by the light emitting element is transmitted into the fluid in the inner volume of the at least one tube by at least one primary light connecting element through the first opening of the tube (col. 5, lines 31-37);

further wherein the light guided through the fluid in the inner volume of the tube is transmitted to the light detecting element by the secondary light connecting element (col. 5, lines 37-47); and

further wherein the variation of light detected by the detecting element relates to the amount of target bound to the binding agent on the inner surface of the tube of the measuring cell (col. 3, lines 42-54).

Liu fails to teach the light emitting element being an array of light emitting elements.

Evans teaches a system comprising: a light emitting element that is an array of laser elements (col. 7, lines 60-67; col. 7, line 5); primary and secondary light connecting elements (two bundles of fibers, top bundle is primary light connecting element, col. 7, lines 4-5; Fig. 20); measuring cells (ducts, col. 7, line 5); and light detecting elements (detector array indicates multiple detectors, col. 7, lines 6-7), wherein the emitted light is transmitted into the inner volume of the measuring cell through the primary light connecting element through a first opening of the measuring cell and the light guided through the measuring cell is transmitted to the light detecting element by the secondary light connecting element that is connected to a second end of the measuring cell (Fig. 20), in order to provide duplicated testing for confirmation of results.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the single laser as taught by Liu, with an array

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of laser light emitting elements along with an array of measuring cells as taught by Evans, in order to provide detection of different analyte in a sample (col. 8, lines 39-65).

With respect to claims 16 and 17, Liu teaches the light detecting element being a photodiode (col. 5, lines 40-42) or photodiode array (col. 5, lines 44-46).

With respect to claim 18, Liu teaches the fibers attached to the measuring cell through openings in the tube, these openings can be considered optical windows (where fibers 18 and 20 are attached to tube 10 there is a hole in tube 10, which is considered an optical window, Fig. 3).

Regarding claim 20, Liu teaches the primary and secondary light connecting elements integrated into the measuring cell (optical fibers 18 and 20 are integrated into the capillary, Fig. 3).

With respect to claims 24, 27 and 28, Liu teaches that the fluid is liquid (col. 2, line 61 and 67), the ability of the tube to guide light is due to the structure of the inner surface of the tube (col. 2, line 61-col. 3, line 9) and the inner surface of the tube comprises one or more layers that are organic and inorganic materials (layers 24, 12 and 14, Fig. 2; col. 3, lines 1-9; col. 3, line 24-26; col. 3, lines 33-35).

Regarding claims 25 and 26, Liu teaches the tube being a capillary tube and therefore the fluid is regulated by gravity capillary forces (col. 2, lines 63-64; col. 4, lines 41-45).

Regarding claim 29, Liu teaches the tube being a fluid core waveguide (col. 2, line 61).

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With respect to claim 30, Liu teaches the binding agent directly bound to the inner surface of the tube (col. 4, lines 33-35).

With respect to claim 33, Liu teaches the inner surface of the tube having a layer that interacts with the at least one bound target in such a way that it changes the properties of the light guided through the tube (col. 3, lines 55-59 and col. 3, line 63-col. 4, line 14).

Regarding claim 59 and 60, Liu teaches a material, which is a feature, surrounding the tube, wherein the material results in the tube guiding light through a fluid in the inner volume of the tube, col. 3, lines 1-9 and 24-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 19, 21, 22, 31 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (US 6,020,207) in view of Lockhart (US 6,974,673).

Liu teaches a system comprising a capillary tube having a first and second opening that are connected to primary and secondary light connecting elements and teach separate fluid dispensing elements (represented by up and down arrows into the tube, 10, in Fig. 3), but fail to teach each the light connecting elements also being fluid dispensing elements connected to a sample reservoir.

Lockhart teaches a system comprising: a sample reservoir (sample container, col. 7, lines 55-58) connected to a tube having a first and second opening (142 and 144, Fig. 1) and an inner surface of the tube coated with a binding agent (col. 2, lines 31-42), wherein a primary and secondary light connecting element are connected to the first and second ends of the tube (col. 4, lines 10-19) and the light connecting element is also a fluid dispensing element that is capable of transferring fluid to and from the tube (col. 4, lines 20-25, Fig. 1), wherein a target is introduced into the tube by loading a fluid comprising the target through the first opening of the tube (target substance enters cavity through port, col. 4, lines 20-25; port contains light emitting element and is the first end of the tube, col. 4, lines 10-19), in order to provide a flow cell.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the fluid dispensing elements of the tube as taught by Liu, into the first and second openings into the tube which are also connected to the primary and secondary light connecting elements as taught by Lockhart, in order to provide a simple and consolidated method of transporting a sample to the tube.

With respect to claim 31, Liu does not specifically teach an interstitial layer between the binding agent and the inner surface of the tube.

Lockhart teaches a binding agent directly attached to the inner surface of the tube (waveguide is tube, col. 9, lines 20-27) or the binding agent indirectly attached to the inner surface of the tube via a linker (linker is an interstitial layer and waveguide is tube, col. 9, lines 27-55), in order to provide attachment of the binding agent to the inner surface of the waveguide.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to add to the tube of Liu, an interstitial layer between the binding agent and the inner surface of the tube as taught by Lockhart. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent attachment technique and since the same expected attachment effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (US 6,020,207) in view of Saaski et al. (US 6,484,594).

Liu teaches a tube having an inlet and outlet, but fail to specifically teach the outlet connected to a disposal reservoir.

Saaski et al. teach the use of a waste container (column 30, lines 40-45), in order to clear old, historical target material is important in any situation where it is desired that the detection apparatus detect target material that is currently entering the invention, rather than target material that has entered it in the past (column 30, lines 43-65). `

Therefore, it would have been obvious to one of ordinary skill in the art to have a

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waste container (disposal reservoir) in the invention of Liu and that the fluid exiting the waveguide of Liu go to a waste container, as taught by Saaski et al, in order to clear the waveguide of old, historical target material, such that the detection apparatus provides more accurate detection by detecting target material currently entering the waveguide rather than target material that has entered it in the past.

6. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (US 6,020,207) in view of Bohnenkamp (US 6,252,657).

Liu teaches a measuring cell that comprises a tube having a binding agent immobilized to the inner surface, but fail to specifically teach a layer that prevents or retards non-specific adsorption.

Bohnenkamp teaches a light guiding capillary (col. 2, lines 50-55) having analytes fixed to the inner surface of the capillary (col. 1, lines 49-55) and the excess of binding areas covered with inert protein (col. 3, lines 15-20), in order to prevent non-specific binding.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to add to the tube of Liu, a layer that prevents non-specific adsorption of other components in the fluid as taught by Bohnenkamp, in order to provide more accurate detection by preventing non-specific binding of non-target analyte to the inner surface of the tube.

Response to Arguments

7. Applicant's arguments with respect to claims 13, 16-33, 59, 60 and 62 have been considered but are moot in view of the new ground(s) of rejection. The previous

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rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment requiring the new limitation of an array of light emitting elements, which is taught in the prior art by Evans as described above.

8. The previous double patenting rejections have been withdrawn in light of the Terminal Disclaimer filed 12 November 2008.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641